United States Department of
Health & Human Services
Office of the Assistant Secretary for Preparedness and Response (ASPR)

ROLES OF EXISTING TECHNOLOGOLGIES AND ADJUVANTS

Sustainable Influenza Vaccine Production Capacity
Stakeholders' Workshop
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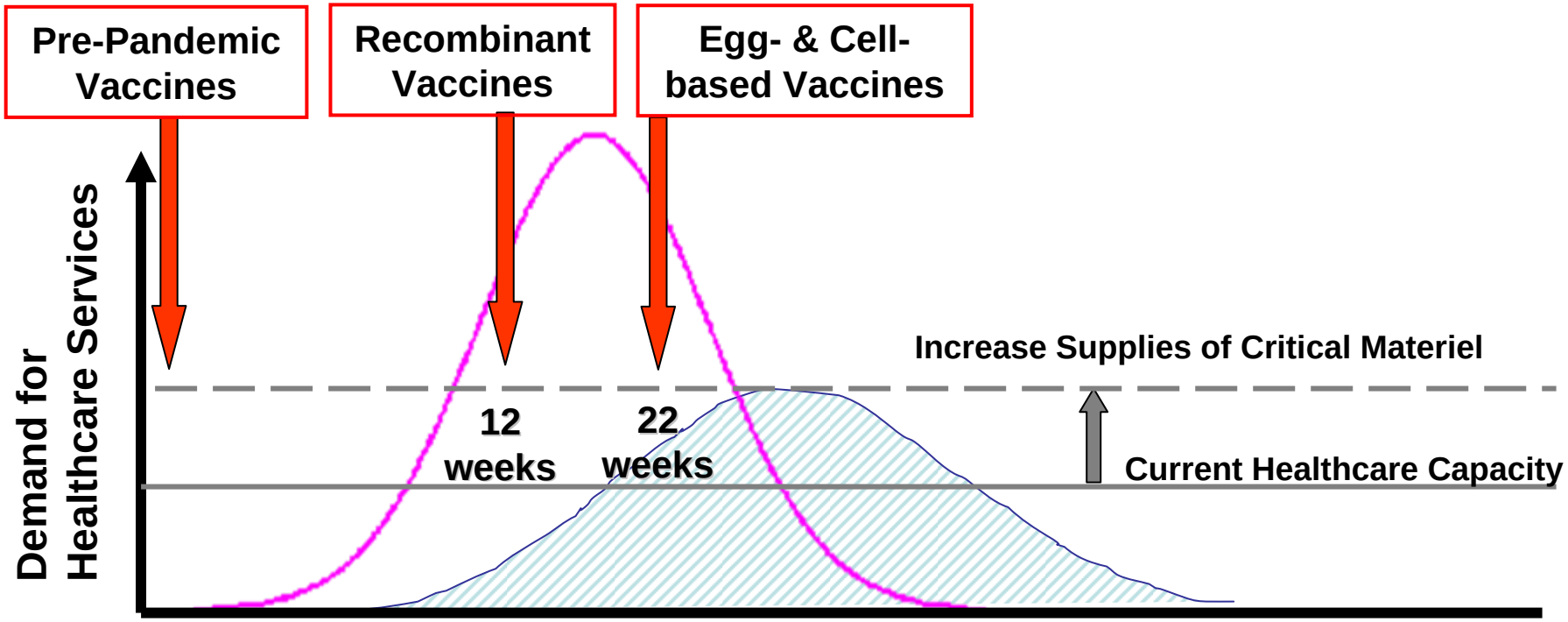
HHS/ASPR/BARDA

Pandemic Influenza MCM Supply-Demand Gap Closure

Reduce Demand: Pre-Pandemic Vaccines, Community Mitigation, Antivirals, Vaccines, Masks

Increase Capacity: Ventilators, Oxygen, Antivirals, Pandemic Vaccines, Masks,



Egg-based Vaccines

- **Provide > 99% of current seasonal & pandemic influenza vaccine manufacturing capacity globally**
- **Vaccine safety and effectiveness history > 50 years**
- **Incumbent industry**
  - Virus reference strains
  - Vaccine manufacturing processes & facilities
  - Vaccine potency & immunogenicity assays
  - Vaccine acceptance
- **Specialized manufacturing facilities for bulk production**
- **Vulnerabilities**
  - Avian pathogens
  - Egg supply
  - Virus strain growth
- **Co-existence with newer vaccine technologies**

Adjuvants

- **Aluminum hydroxide provides limited dose-sparing effects**
- **Oil-in-Water adjuvants**
  - Dose-sparing effects
  - Cross-reactive immunity among virus strains
  - Enhanced priming-effects
  - Limited licensure in wide populations
  - Variable vaccine acceptance
  - H1N1 pandemic effects
  - IP issues
- **Other adjuvants**
- **Primary means to achieve sustainable influenza vaccine production to accommodate facility size demands for seasonal vaccine & future pandemic surge capacity needs**